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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/550,453	08/18/2006	Gina Fischer	028232-0113	3166

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EXAMINER	
SASAN, ARADHANA	
ART UNIT	PAPER NUMBER
1615	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/550,453	FISCHER ET AL.	
	Examiner	Art Unit	
	ARADHANA SASAN	1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *09 February 2010*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *64-81* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *64-81* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *2/9/10 and 7/16/09*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Status of Application

1. The remarks and amendments filed on 02/09/10 are acknowledged.

2. Claims 1-63 were cancelled.

3. Claims 64, 77 and 78 were amended.

4. Claims 64-81 are included in the prosecution.

Information Disclosure Statement

5. The information disclosure statement (IDS) submitted on 02/09/10 is acknowledged.

6. Regarding the IDS filed on 07/16/09, Applicant provided the English language equivalents for documents A34 (DE 2332484 – English equivalent GB 1430684) and A35 (DE 2415490 – English equivalent US 3,957,523).

7. The submissions are in compliance with the provisions of 37 CFR 1.97 and 1.98. Accordingly, the examiner is considering the information disclosure statements. See attached copies of PTO-1449.

Response to Arguments

Objection to the Specification

8. In light of the amendments to the Specification, the objection of 11/10/09 is withdrawn.

Claim Objection

9. In light of the amendment of claim 77, the objection of 11/10/09 is withdrawn.

Rejection of claims under 35 USC § 112, 1st paragraph

10. Applicant's arguments, see Page 10, filed 02/09/10, with respect to the rejection of claims 64-77 and 79-81 under 35 USC § 112, first paragraph as failing to comply with the enablement requirement have been fully considered and are persuasive. Therefore, the rejection has been withdrawn.

Rejection of claims under 35 USC § 112, 2nd paragraph

11. In light of the amendments of claims 64 and 78, the rejection of these claims under 35 USC § 112, second paragraph is withdrawn.

12. Applicant's arguments, see Page 11, filed 02/09/10, with respect to the rejection of claim 67 under 35 USC § 112, second paragraph (as being indefinite for the recitation of "less side effects") have been fully considered but are not persuasive. Applicant argues that the advantageous properties achieved by the present invention may be associated with fewer side effects, that such side effects are routinely assessed and reported in clinical trials, and that those skilled in the art will not find the recitation of "less side effects" to be indefinite. This is not persuasive because "fewer side effects" is different from "less side effects." The former is quantifiable whereas the latter is a measure of degree. Claim 67 recites "less side effects" not "fewer side effects." Also, on Page 3, lines 31-34 of the specification, "less frequently reported side effects" are disclosed. Therefore, the rejection is maintained.

Rejection of claims under 35 USC § 102(b)

13. Applicant's arguments, see Page 12, filed 02/09/10, with respect to the rejection of claims 64-65 and 79-81 under 35 USC § 102(b) as being anticipated by Bar-Shalom

et al. (US 5,213,808) have been fully considered and are persuasive. Therefore, the rejection has been withdrawn.

Rejection of claims under 35 USC § 102(e)

14. Applicant's arguments, see Page 12, filed 02/09/10, with respect to the rejection of claims 64-68 and 76-81 under 35 USC § 102(e) as being anticipated by Fischer et al. (US 2004/0253310 A1) have been fully considered but are not persuasive. Applicant argues that Fischer does not qualify as a prior art reference under 35 USC § 102(e) because it is not an application filed by "another." Applicant argues that Fischer names the same inventors as the instant application: Gina Fischer, Daniel Bar-Shalom, Lillian Slot and Christine Jensen. This is not persuasive because the inventive entity of the Fischer reference is different. The common inventors between the instant application and the Fischer reference are Gina Fischer, Daniel Bar-Shalom, and Lillian Slot. However, Christine Jensen is not the same as Christine Andersen. Since the Fischer reference is by another, it is properly used as a 35 USC § 102(e) reference. Therefore, the rejection is maintained.

Rejection of claims under 35 USC § 103(a)

15. Applicant's arguments, see Page 13, filed 02/09/10, with respect to the rejection of claims 69-75 under 35 USC § 103(a) as being unpatentable over Fischer et al. (US 2004/0253310 A1) have been fully considered but are not persuasive. Applicant argues that Fischer does not qualify as prior art against the instant application because it is not an application filed by "another." Applicant argues that Fischer cannot be applied against the pending claims in a § 103 rejection. This is not persuasive because the

inventive entity of the Fischer reference is different. The common inventors between the instant application and the Fischer reference are Gina Fischer, Daniel Bar-Shalom, and Lillian Slot. However, Christine Jensen is not the same as Christine Andersen. Since the Fischer reference is by another, it is properly used as a 35 USC § 102(e) type reference in a 35 USC § 103(a) rejection. Therefore, the rejection is maintained.

16. Applicant's arguments, see Page 13, filed 02/09/10, with respect to the rejection of claims 66-78 under 35 USC § 103(a) as being unpatentable over Bar-Shalom et al. (US 5,213,808) in view of Fischer et al. (US 2004/0253310 A1) have been fully considered and are persuasive since the Bar-Shalom reference includes surface active agents. Therefore, the rejection is withdrawn.

Rejection of claims under Obviousness-type Double Patenting

17. Applicant's arguments, see Pages 13-14, filed 02/09/10, with respect to the provisional rejection of claims 64-81 on the ground of non-statutory obviousness-type double patenting as being unpatentable over claims 1, 3-47, and 49-71 of co-pending Application No. 10/550,685 and the provisional rejection of claims 64-81 on the ground of non-statutory obviousness-type double patenting as being unpatentable over claims 60-100 of co-pending Application No. 12/078,312 have been fully considered. Applicant notes that these are provisional rejections, and therefore defer these issues until the application is otherwise in condition for allowance. Since there are conflicting claims in more than one application and there are other pending rejections in this application, the provisional double patenting rejections will be maintained. Please see MPEP § 804, I, B.

MAINTAINED REJECTIONS:

Claim Rejections - 35 USC § 112

18. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

19. Claim 67 **remains** rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

20. Claim 67 recites "less side effects". It is unclear what is considered "less side effects", if there is a minimum requirement for "less side effects" or if there is a measurable or quantifiable scale for the "side effects".

Claim Rejections - 35 USC § 102

21. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

22. Claims 64-68 and 76-81 **remain** rejected under 35 U.S.C. 102(e) as being anticipated by Fischer et al. (US 2004/0253310 A1).

The applied reference has a common inventor with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 102(e) might be overcome either by a showing under 37 CFR 1.132 that any invention disclosed but not claimed in

the reference was derived from the inventor of this application and is thus not the invention "by another," or by an appropriate showing under 37 CFR 1.131.

Fischer teaches a method for treating a patient suffering from pain comprising administering an opioid in a controlled release composition, the composition comprises a matrix comprising an opioid, a polymer or a mixture of polymers, optionally one or more pharmaceutically acceptable excipients and a coating with at least one opening (Page 17, claim 1, Page 19, claims 54-58). "The active substance is released into an aqueous medium by erosion of at least one surface of the composition ... the ... active substance is typically an opioid such as morphine or a glucuronide thereof. The coating comprises a first cellulose derivative which is substantially insoluble in the aqueous medium and at least one of a) a second cellulose derivative which is soluble or dispersible in water, b) a plasticizer, and, d) a filler" (Abstract). Figure 4 discloses the results of a pharmacokinetic pilot study where morphine compositions were administered to 16 volunteers (Figure 4, Pages 16-17, [0243] – [0247]). Another study was conducted in patients suffering from chronic pain (Page 17, [0248]). A composition comprising morphine sulfate and polyethylene oxide 200,000 was prepared and dissolution studies show release of morphine sulfate from 1 to 8 hours (Page 15, Example 1, [0231] – [0234]). The use of polyglycols as suitable polymers in the composition is disclosed (Page 5, [0076]). The composition can be administered 1-2 times or 1 times daily (Page 12, [0166]). Measuring the degree of pain treatment by using a 4-point verbal rating scale is disclosed (Page 19, claim 56). Fischer teaches that "... it is possible to obtain zero order release from a polymeric matrix composition

without any content of a water dispersible or water soluble surface active agent or a mixture of such surface active agents ..." (Page 3, [0044]).

Therefore, all the limitations of claims 64-68 and 76-81 are anticipated by the teachings of Fischer.

Claim Rejections - 35 USC § 103

23. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

24. Claims 69-75 **remain** rejected under 35 U.S.C. 103(a) as being unpatentable over Fischer et al. (US 2004/0253310 A1).

The teaching of Fischer is stated above.

Fischer does not expressly teach the mean plasma concentration after various time periods that is a percentage of the mean maximal concentration obtained by the dose.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to use the method of treating pain by administering a composition comprising morphine sulfate in a matrix comprising polymers and a coating having at least one opening, as suggested by Fischer, determine the mean plasma concentration over different time periods during the process of routine experimentation, and produce the instant invention.

One of ordinary skill in the art would do this because Fischer teaches the determination of plasma concentration (Figure 4). One of ordinary skill in the art would find it obvious to determine the mean maximal concentration obtained by a particular dose and the percent of that dose for a particular time point.

From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

The limitations of claims 69-75 related to the mean plasma concentration after specific time periods are rendered obvious by the results of the study shown in Figure 4 (plasma concentration of morphine sulfate over 24 hours) by Fischer.

Double Patenting

25. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to

be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

26. Claims 64-81 **remain** provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 3-47, and 49-71 of copending Application No. 10/550,685 (the '685 Application).

Although the conflicting claims are not identical, they are not patentably distinct from each other because instant claims and claims of the '685 Application are drawn to coated matrix composition. The difference between instant claims and those of the '685 Application is that instant claims are drawn to a method of treating a patient suffering from pain. However, instant claims were amended to include the limitations of a coated matrix composition for administration. Thus, the limitations of the coated matrix composition are obvious over claims of the '685 Application, and thus they are not patentably distinct over each other.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

27. Claims 64-81 **remain** provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 60-100 of copending Application No. 12/078,312 (the '312 Application).

Although the conflicting claims are not identical, they are not patentably distinct from each other because instant claims and claims of the '312 Application are drawn to

coated matrix composition and a method of treating a patient suffering from pain. The difference is that claims of the '312 Application require specific excipients in the matrix composition. However, one of ordinary skill in the art would find it obvious to use various pharmaceutically acceptable excipients in the matrix composition based on the compatibility of the excipient with the chosen active ingredient and the recited excipients of the '312 Application would be obvious variants. Thus, the claims directed to a method of treatment of a patient suffering from pain by administering a coated matrix composition are obvious over claims of the '312 Application, and thus they are not patentably distinct over each other.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Conclusion

28. No claims are allowed.

29. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

30. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Aradhana Sasan whose telephone number is (571) 272-9022. The examiner can normally be reached Monday to Thursday from 6:30 am to 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert A. Wax, can be reached at 571-272-0623. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Aradhana Sasan/
Examiner, Art Unit 1615

/Humera N. Sheikh/
Primary Examiner, Art Unit 1615